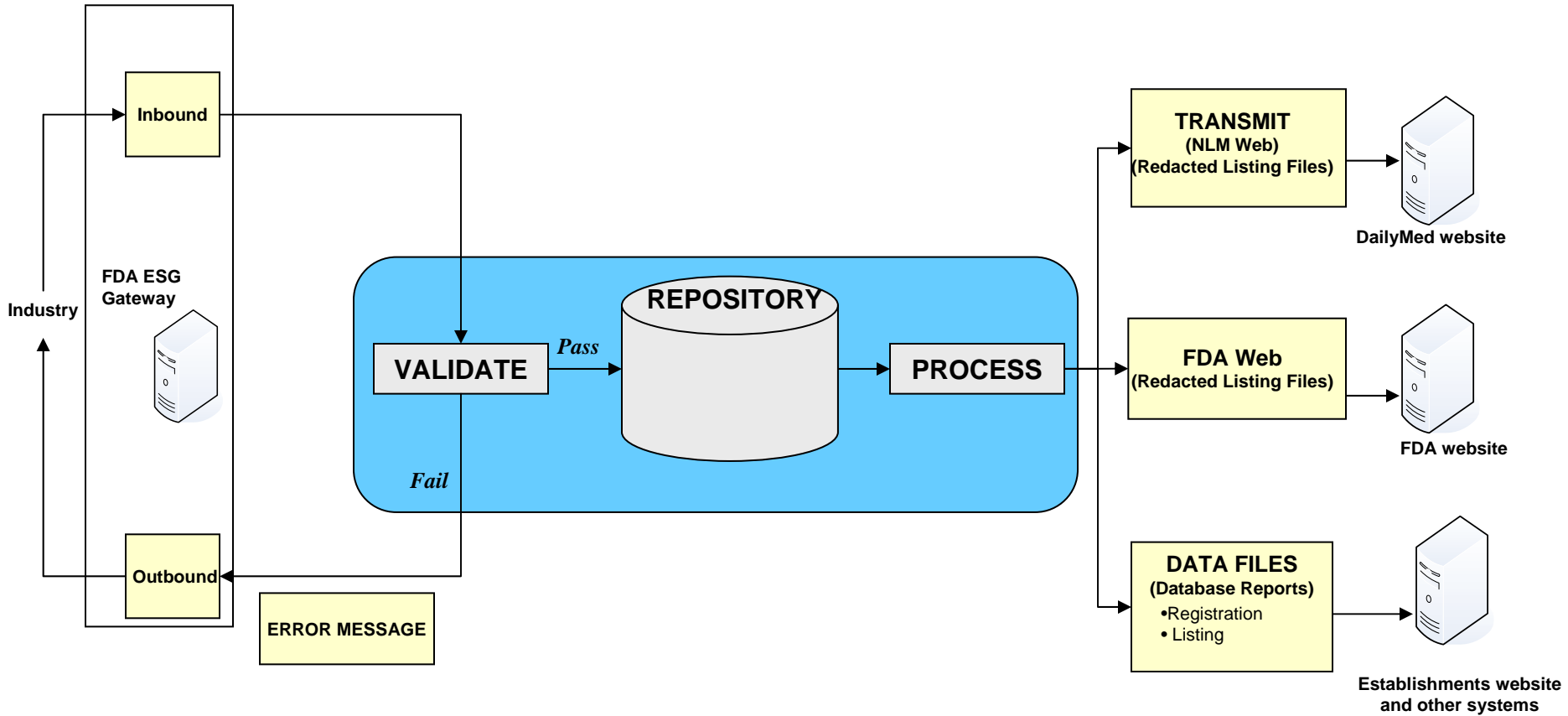


Preparing Electronic NDC Labeler Code & Drug Establishment Registration Submissions in SPL Format

Lonnie Smith
Policy Analyst
FDA Data Standards Council



eLIST



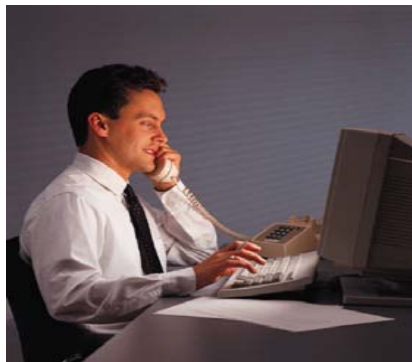
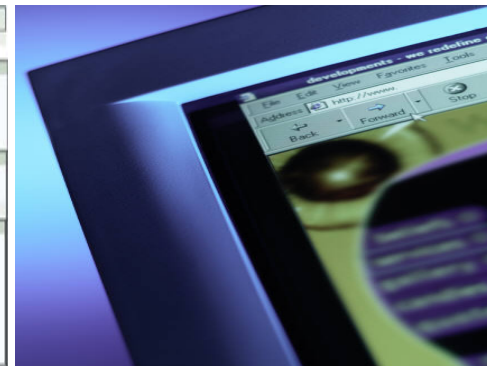
Selecting an SPL Authoring Tool or Solution

- Utilize SPL authoring software with features which assist with the entry and validation of data: Various SPL authoring software
- Provide data to SPL conversion service which create the SPL files and submit the files for you.
- Create SPL document using free fillable forms: SPL Xforms
- SPL software or conversion vendors - <http://spl-work-group.wikispaces.com/Vendors>
- SPL Xforms - <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm189651.htm>
- Whichever option you choose should result in the creation of valid SPL documents.

• **SPL Conversion Vendor**

SPL Xforms

SPL Authoring Software

A screenshot of a web form titled "HL7 SPL - NDC Labeler Code Request v1.00". The form has tabs for "Open", "Save As", and "Save". It is divided into sections: "Document Information" with fields for ID, Set ID, Version Number, and Effective Time; "Labeler" with fields for Name and NDC Number; and "Contact" with fields for Name, Mailing Address, City, State, Country, Postal Code, Telephone Number, and Email Address. There are also buttons for "Add NDC Labeler Code" and "Delete NDC Labeler Code".

Technical Terms Glossary

Term	Definition
Core ID	A unique identifier which the FDA ESG assigns to every submission and uses for reference purposes
Document Root ID	Globally Unique Identifier (GUID) and is unique for each version of the document. Also referred as “root ID,” “ID,” “document ID,” or “document root ID.”
Effective Time	Provides a date reference to the SPL document version or a section including the year, month and day as yyyyymmdd.
GUID	Globally Unique Identifier (used as the SPL document root ID, setID, or section IDs)
SetID	Globally Unique Identifier (GUID) and is a unique identifier for the document that remains constant through all versions/revisions of the document.
UUID	Universal Unique Identifier (UUID) Synonymous w/GUID (see definition for GUID)
Version Number	Integer greater than zero that provides a sequence to the versions of the document.

NDC Labeler Code Request – Request for an NDC Labeler Code

Acme Inc -----

Labeler's Name

9-digit DUNS Number - No hyphens

Missing labeler code - This is a request for a labeler code.

Product Information			
Product Type		NDC LABELER CODE REQUEST	
Labeler - Acme Inc (752913821) NDC Labeler Code:			
Contact	Address	Telephone Number	Email Address
Sherry Thompson	Address: 325 Fairway Avenue City, State, Zip: Towson, MD, 20221 Country: USA	+1-888-521-2958	sherry.thompson@acme.com

Revised: 03/2010

Contact Person's

Address for contact person

Telephone number using correct format

E-mail address using correct format

Acme Inc

NDA Labeler Code SPL with already assigned NDC Labeler Code

Acme Inc

Already assigned 4- or 5- digit Labeler code
(No leading zeros which form a 6-digit labeler code)

Product Information

Product Type

NDC LABELER CODE REQUEST

Labeler - Acme Inc (752913821) **NDC Labeler Code:** 76182

Contact	Address	Telephone Number	Email Address
Sherry Thompson	Address: 325 Fairway Avenue City, State, Zip: Towson, MD, 20221 Country: USA	+1-888-521-2958	sherry.thompson@acme.com

Revised: 03/2010

Acme Inc

Establishment Registration SPL

Company for owner/operator of drug establishment(s)				Registrant's DUNS Number		Document Type	
Product Information							
Product Type				ESTABLISHMENT REGISTRATION			
Registrant - Acme Inc (871192812)							
Contact		Address		Telephone Number		Email Address	
Paul Jacobsen		Address: 17 Philadelphia Avenue City, State, Zip: Towson, MD, 19001 Country: USA		+1-888-201-5821		paul.jacobsen@acme.com	

Registrant contact person's name

Contact person's address

Contact person's telephone number

Contact person's e-mail address

Establishment Located in USA

Establishment's name		DUNS Number (9-digit) No hyphens	FEI Number (7- or 10-digits)	Type of operation (except US Agent and Import)
Establishment				
Name	Address	ID/FEI	Operations	
Acme Manufacturing USA	Address: 17 Philadelphia Avenue City, State, Zip: Towson, MD, 19001 Country: USA	441912813/3000149281	manufacture	
Contact	Address	Telephone Number	Email Address	
Paul Jacobsen	Address: 17 Philadelphia Avenue City, State, Zip: Towson, MD, 19001 Country: USA	+1-888-201-5821	paul.jacobsen@acme.com	

Establishment contact person

Establishment contact's address

Contact's telephone number

Contact's e-mail address

2-letter state abbreviation

3-letter country code

Foreign Drug Establishment

Establishment			
Name	Address	ID/FEI	Operations
Acme Manufacturing - France	Address: 314 Provence Rue City, State, Zip: Nice, -, 33151 Country: FRA	999210521	manufacture, api manufacture
Contact	Address	Telephone Number	Email Address
Etienne Bouvier	Address: 19 Champs Elysees City, State, Zip: Paris, -, 151295 Country: FRA	+32-592-5821	etienne.bouvier@acme.fr
US Agent (ID)	Address	Telephone Number	Email Address
Templeton Agents (594921022)		+1-888-125-5821	jan.tolson@templeton.com
Importer (ID)	Address	Telephone Number	Email Address
Franklin Imports (075821321)		+1-444-291-5921	james.costas@franklin.com

Establishment's name

Enter dash "-" if there is no state

DUNS Number (9-digit)

Missing FEI indicates request for FEI

Multiple types operation permitted if applicable (except US agent or Import)

3-letter country code

Revised: 03/2010

Current registration year
Enter format as
YYYYMMDD

US agent must be present
if country code is not
"USA"

Import company name &
DUNS Number

Establishment contact's address
does not have to be identical to
establishment's address

Drug Establishment Ownership Changes - Owner/Operator of Multiple Drug Establishment

- To indicate transfer of ownership for one of many drug establishments in a previously submitted Establishment Registration (ER) SPL document
 - Remove the drug establishment from the previous owner's ER SPL document and submit updated file
 - Add the drug establishment to the new owner's ER SPL document and submit updated file (retain original setID)

Drug Establishment Ownership Changes - Owner/Operator of Only One Drug Establishment

- To indicate transfer of ownership for one drug establishment submitted Establishment Registration (ER) SPL document when registrant has only one drug establishment:
 - Submit Out of Business Notification SPL
 - Add the drug establishment to the new owner's ER SPL document and submit updated file (retain original setID)

Current Registration Year

- Subset of data from Establishment Registration SPL file populates the Drug Firm Annual Registration Status website
- **Current registration year is extracted from effective time field of Establishment Registration SPL document**
- Example: effective time 20110105
- Current registration on web: 2011

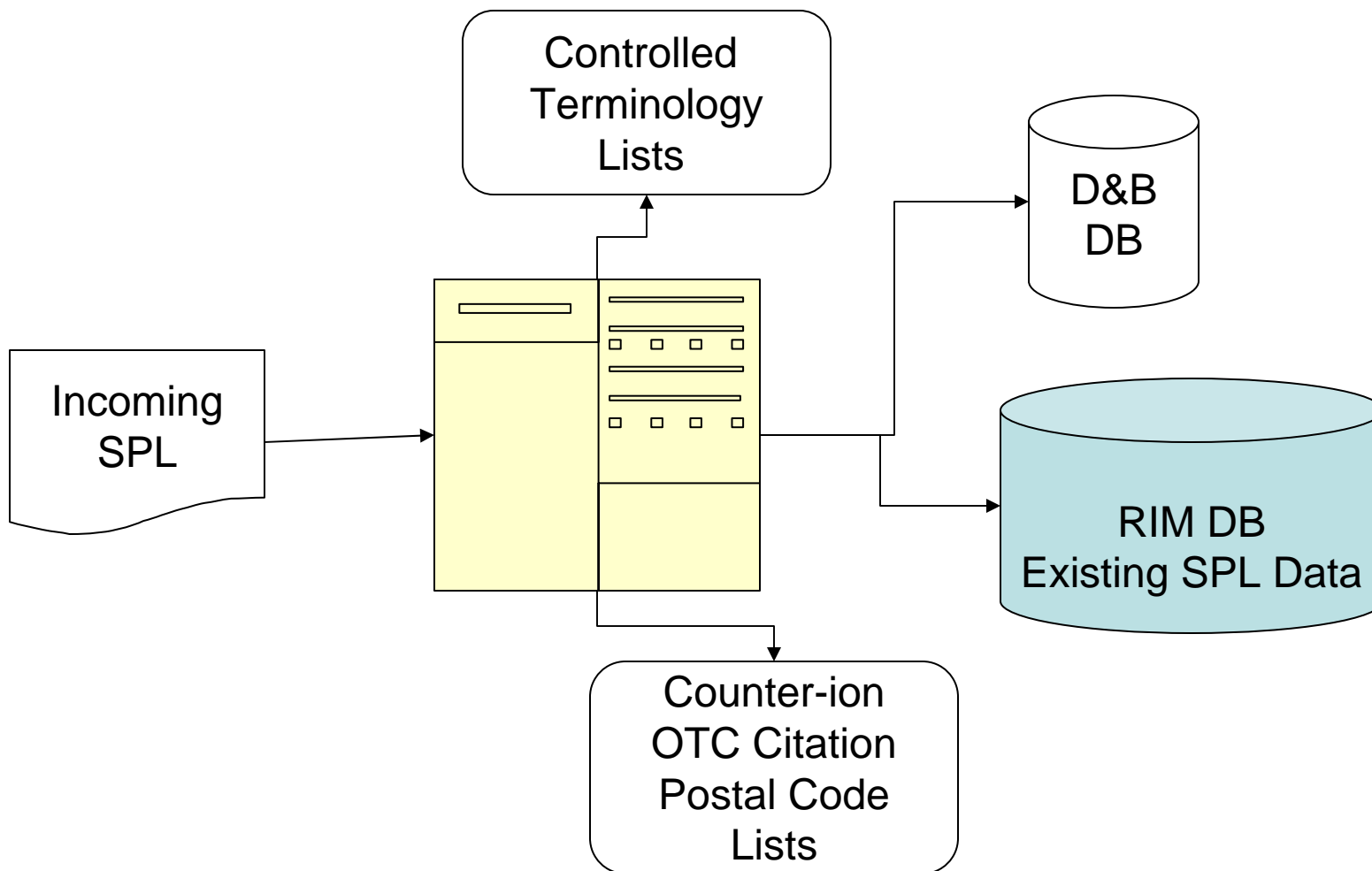
DUNS Number Validation

- DUNS Number in incoming establishment registration SPL file is validated using D&B database
- Validates:
 - Name (or Doing Business As Name)
 - Drug establishments complete address
 - DUNS Number

Registration Notes

- “No Change Notification” – acceptable only after receipt of initial electronic Establishment Registration SPL with data for all of your establishments
- Include all drug establishments owned/operated by registrant in one Establishment Registration SPL document.

Validation Model



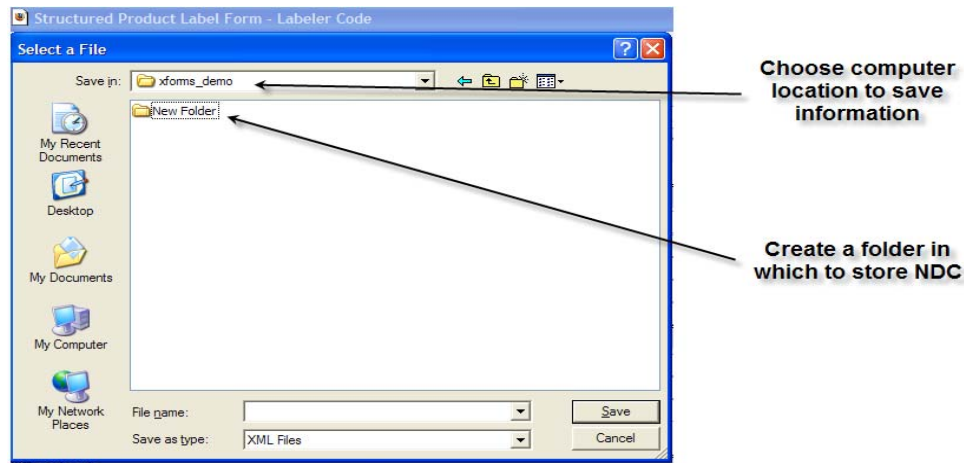
Validation Error Notifications

- Transmitted via FDA Gateway to submitter
- Transmissions occur within 36 hours (business days)
- In the form of a 2nd or 3rd acknowledgment
 - 2nd acknowledgment – system-generated message
 - 3rd acknowledgment – manually generated message with additional notes
- No 2nd or 3rd acknowledgment within 24 hours usually denotes that submission was accepted

Updating SPL Document Tracking Information

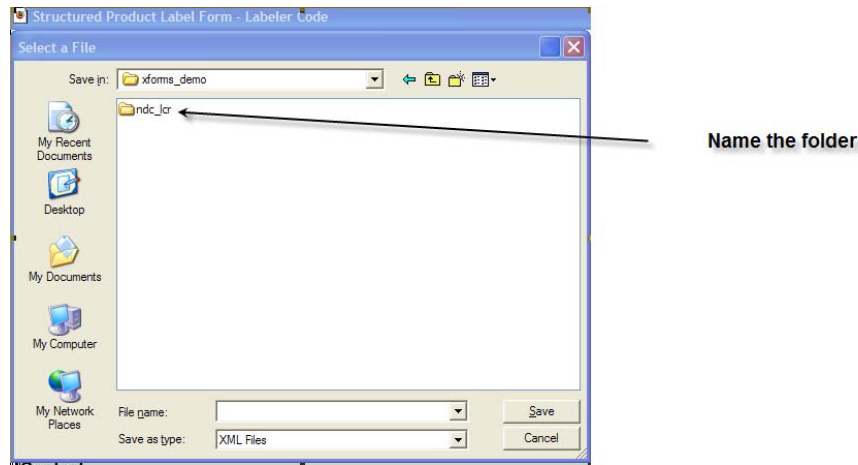
- **Use**
 - **new** id root
 - **new** version number
 - original setId
 - appropriate effective time
- **Misplaced SetID/SPL File**
 - E-mail core ID to spl@fda.hhs.gov
 - Include contact person's name and DUNS Number which were included in original SPL file

Creating the Submission Folder



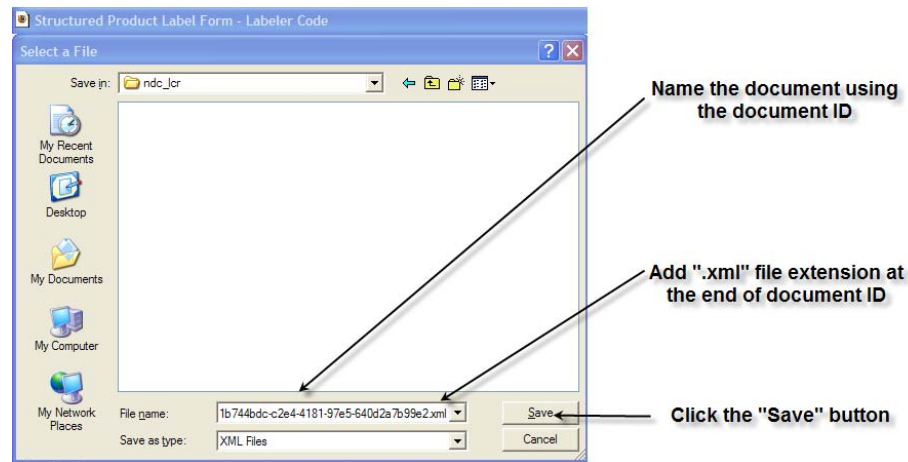
- Choose computer location in which to store folder to contain the SPL file.
- Create a folder in which to store the NDC Labeler Code SPL file.

Naming the Submission Folder



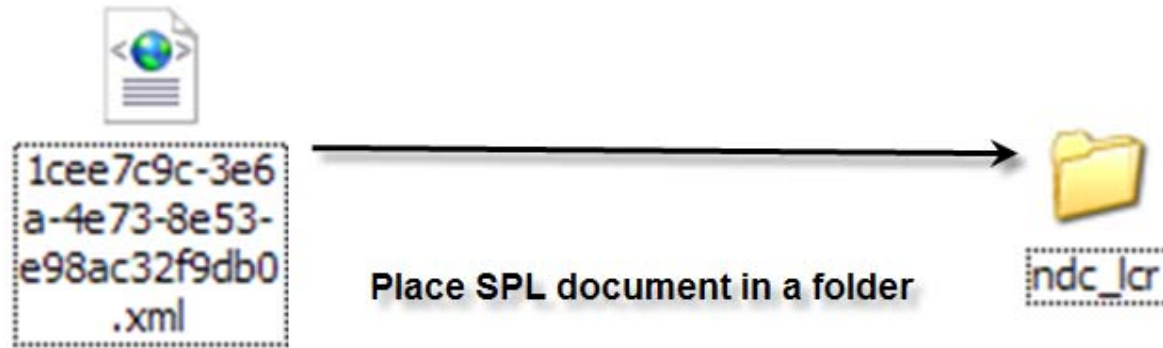
- There is no folder naming convention
- However, we recommend not using symbols in the name of the folder.

Naming the SPL File



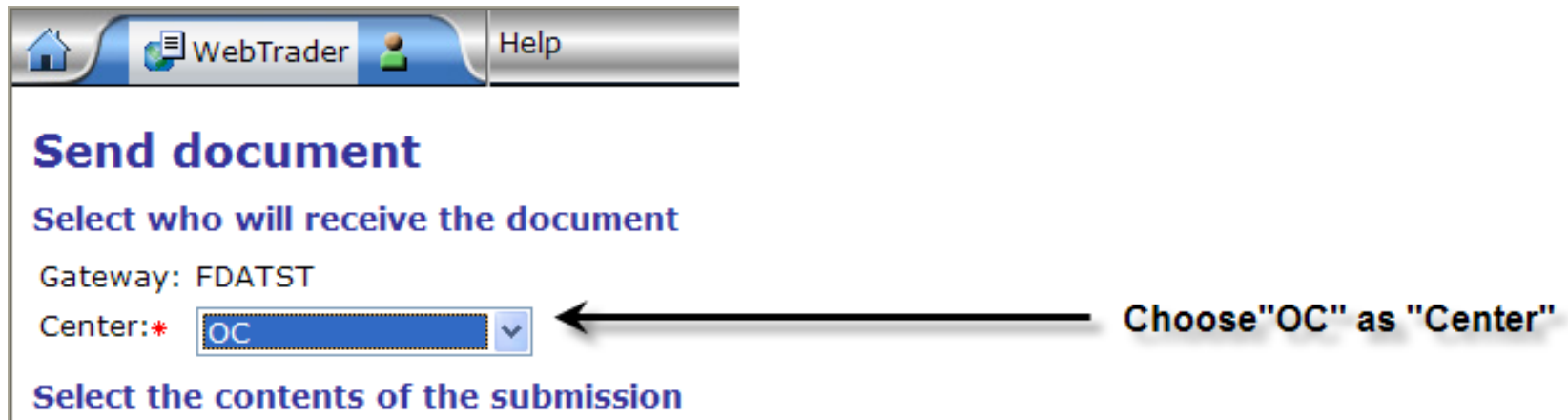
- Use the **document ID** (GUID) as the document file name
- Use “.xml” as the file extension
- Choose “Save” button
- If you do not follow these steps your SPL will **FAIL** validation.

Place SPL File in Folder



- Place SPL document in a folder.
- Ensure that SPL file name is document root ID with “.xml” as file name extension.
- Only **ONE** SPL document per folder. If applicable, image files (jpeg) may accompany listing SPL document in folder.

Choosing “Center”



WebTrader Help

Send document

Select who will receive the document

Gateway: FDATST

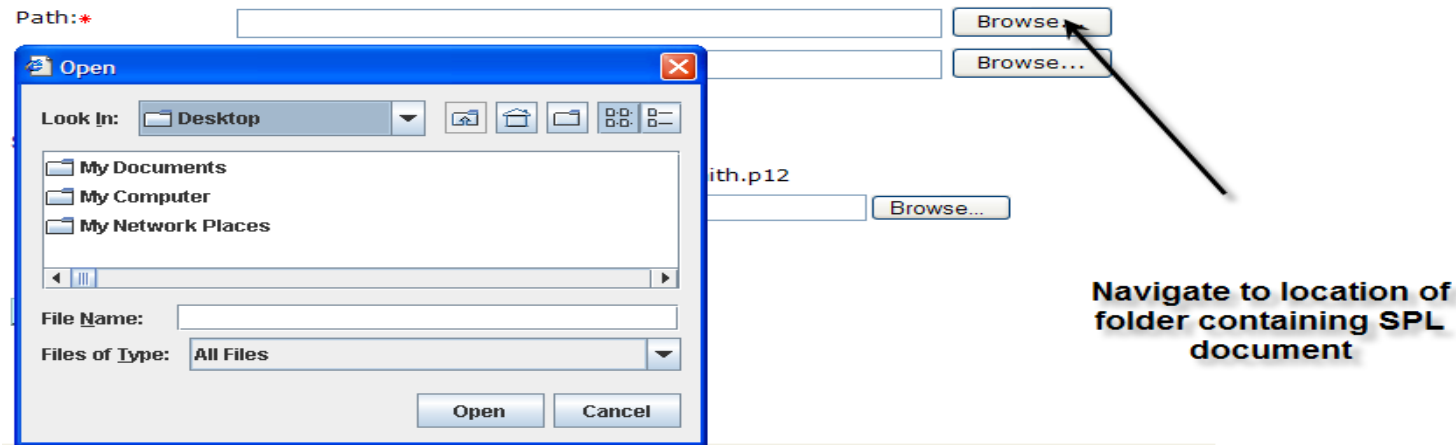
Center: * ▼

Select the contents of the submission

Choose "OC" as "Center"

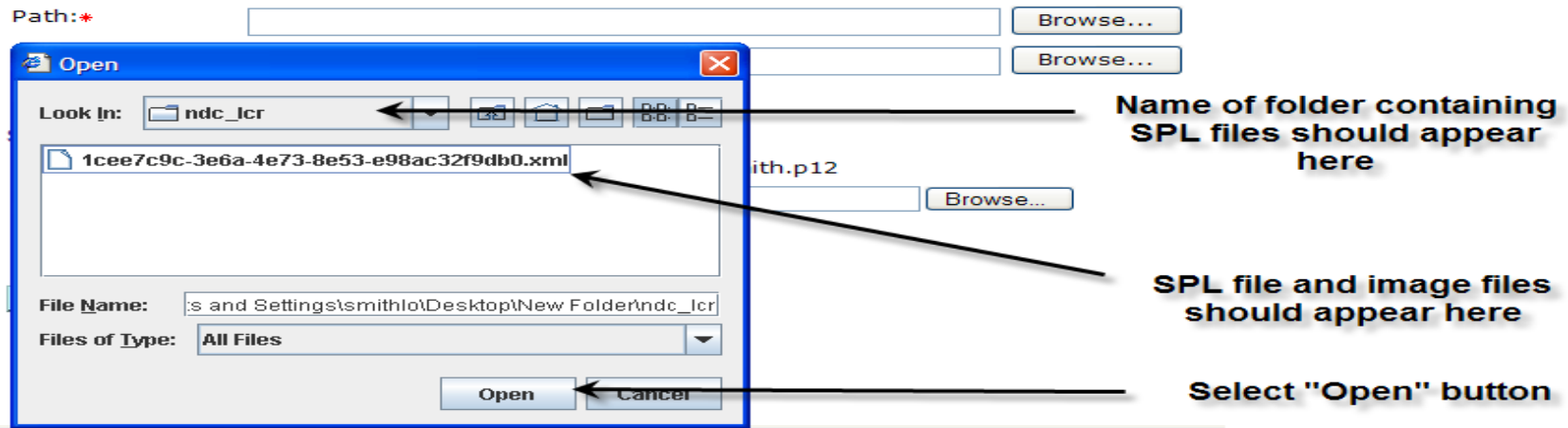
- Select “OC” as the FDA Gateway “center.”
- NDC Labeler Code, Establishment Registration, & Content of Labeling/Listing SPL documents submitted for the purpose of registering a drug establishment and listing a drug product should be sent via “OC.”

Navigate to Folder w/SPL



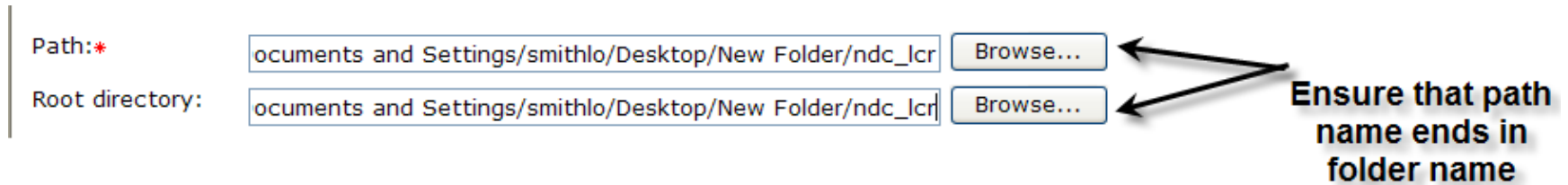
- Click browse button to navigate to location of folder containing SPL file (and, if applicable, associated image files.)

Selecting SPL Submission



- Ensure that you are sending folder.
- Check to be sure that you are not sending a folder within a folder
- Select "Open" to continue.

Checking Path Name



- Ensure that path name ends in the name of folder which contains the SPL document and JPEG files.
- If path ends in file name, then you are only sending the file and not the folder containing files.

Selecting Submission Type

Submission type: * ← **Select submission type "SPL"**

- Use drop-down menu to select submission type “SPL.”
- If submission type “SPL” does not appear, you have chosen the wrong center and not “OC.”

Verify or Select Digital Certificate



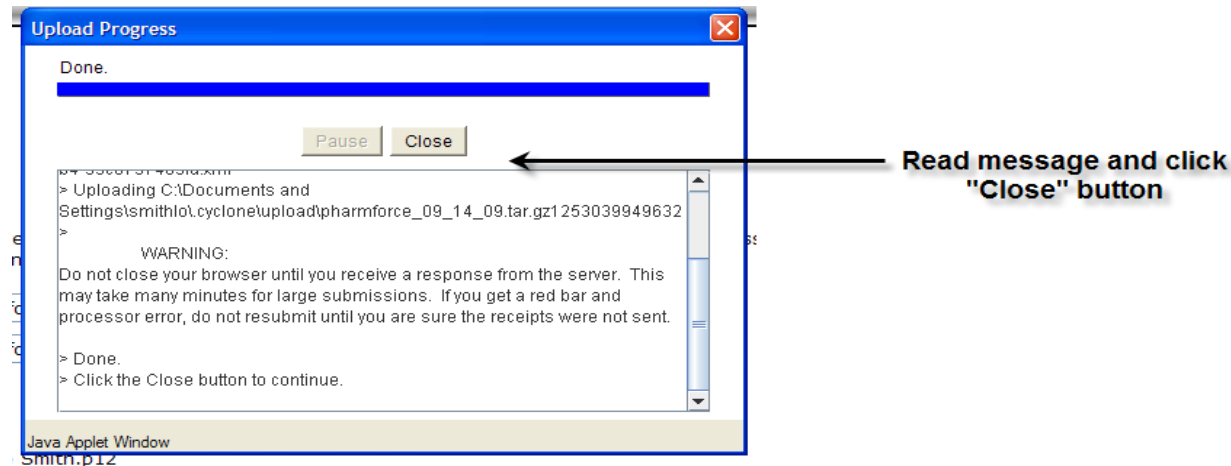
- Verify that your digital certificate is being used.
- Or browse to the location of the digital certificate on your computer.

Sending the Submission



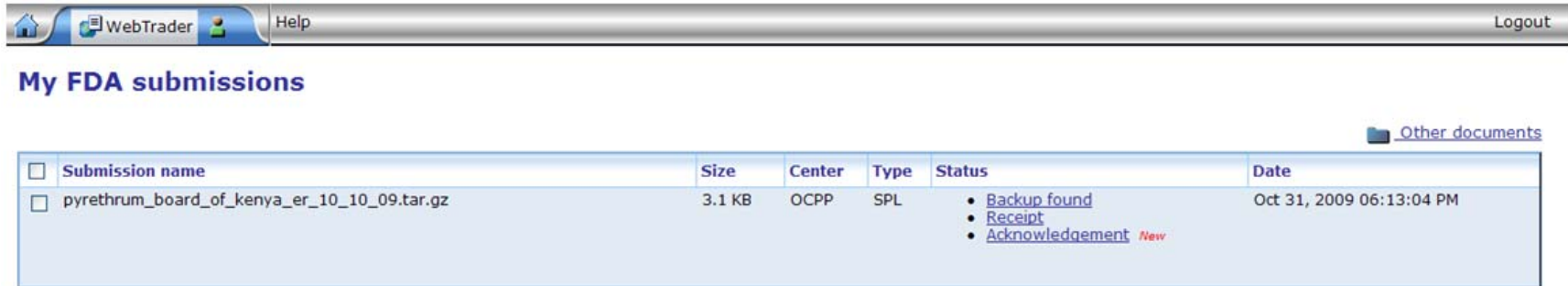
- Select the “Send” button.
- Enter your password to unlock signing certificate.
- Select the “OK” button

Completing Gateway Submission



- Read message in prompt window
- Select "Close" button

Log onto FDA Gateway




The screenshot shows the FDA Gateway WebTrader interface. At the top is a navigation bar with a home icon, 'WebTrader', a user icon, 'Help', and a 'Logout' link. Below this is a section titled 'My FDA submissions'. To the right of this section is a link for 'Other documents'. The main content is a table with columns: Submission name, Size, Center, Type, Status, and Date. One submission is listed: 'pyrethrum_board_of_kenya_er_10_10_09.tar.gz' with a size of 3.1 KB, center OCPP, and type SPL. The status column contains a bulleted list of links: 'Backup found', 'Receipt', and 'Acknowledgement' (marked as 'New'). The date is 'Oct 31, 2009 06:13:04 PM'.

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	pyrethrum_board_of_kenya_er_10_10_09.tar.gz	3.1 KB	OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM

- Log onto the FDA Gateway
- Select the “My FDA submissions” or “Other documents” hyperlinks

Selecting the File w/Core ID

Center	Type	Status	Date
OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM



Click the "Acknowledgment" hyperlink

- The **first** "Acknowledgment" link should take you to window with core ID.

Finding the Core ID

The screenshot shows a table with columns: Size, Center, Type, Status, and Date. The first row is highlighted with a blue background. Below the table, an 'Acknowledgment' window is open, displaying email details. An arrow points to the Core ID in the top left of this window.

Size	Center	Type	Status	Date
3.1 KB	OCPP	SPL	<ul style="list-style-type: none">Backup foundReceipt	Oct 31, 2009 06:13:04 PM

[close](#)


ci1257027185381.4044@lntap02_te.txt

From: [FDATST](#)
To: [Lonnie Smith \(FDA\)](#)
Date: Oct 31, 2009 06:16:03 PM EDT
Submission messageID: <7346727.1257027182095.JavaMail.smithlo@cdl0080685>
[View document](#)


This is the core ID

- After selecting the “Acknowledgment” hyperlink, window should display.
- Core ID is located in top left of “Acknowledgment” window. (.txt is not part of the actual core ID)
- Use this core ID to reference submission when communicating with FDA about status or issue with SPL document.

Finding Error Messages




WebTrader



Help

Logout

My FDA submissions


 [Other documents](#)

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	wellness_center.tar.gz	3 KB	OCP	SPL	<ul style="list-style-type: none">Backup foundReceiptAcknowledgementAcknowledgement <i>New</i>	Oct 31, 2009 03:09:46 PM

- Logon to the FDA Gateway
- Select the “My FDA submissions” or “Other Documents” hyperlinks

Selecting Error Message

Size	Center	Type	Status	Date
3 KB	OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement• Acknowledgement New	Oct 31, 2009 03:09:46 PM



Click on second (or third) "Acknowledgment" hyperlink

- Receipt of a second or third “Acknowledgment” hyperlink is indicative that there is an error with your submission.
- Click on second (and third, if available) “Acknowledgment” hyperlink.

Opening Error Messages

Size	Center	Type	Status	Date
3 KB	OCP	SPL	<ul style="list-style-type: none">Backup foundReceiptAcknowledgement <i>New</i>	Oct 31, 2009 03:09:46 PM

[close](#)

ci1257016187076.9279@lntap01_te.xml

2.8 KB O

From: [FDATST](#)

To: [Lonnie Smith \(FDA\)](#)

Date: Nov 1, 2009 12:34:11 PM EST

Submission messageID: <18012736.1257016184535.JavaMail.smithlo@cdl0080685>

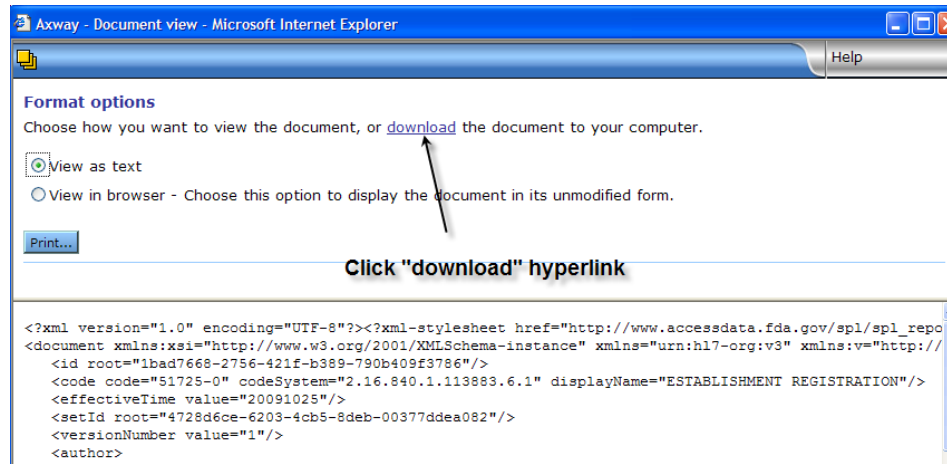
[View document](#)

2.7 KB O

Click "View document" hyperlink

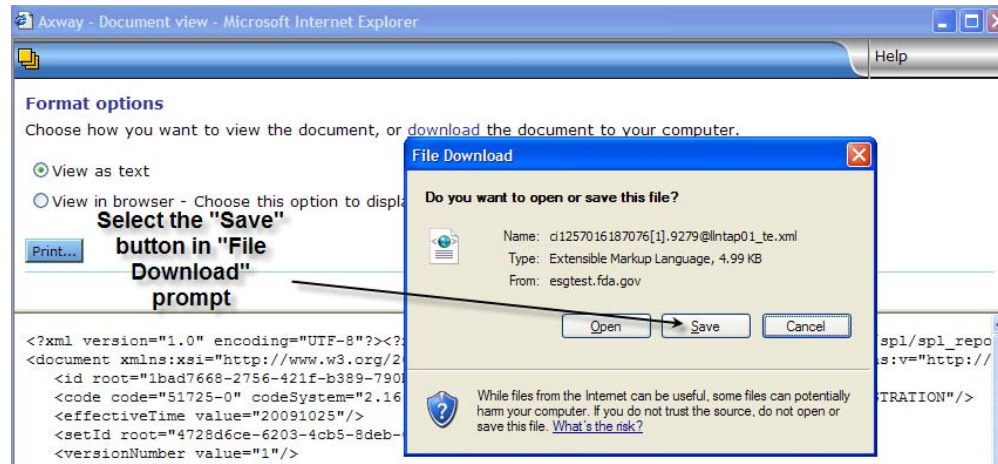
- Click the “View Document” located in the bottom left corner of Acknowledgment prompt window.

Downloading Error Message



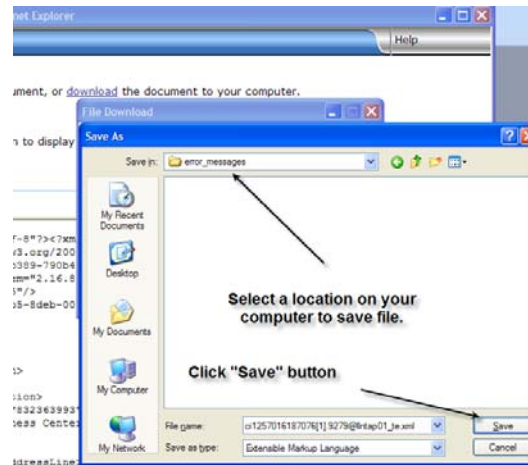
- Select the “download” hyperlink to download the error message to location on computer

Saving the Error Message Document



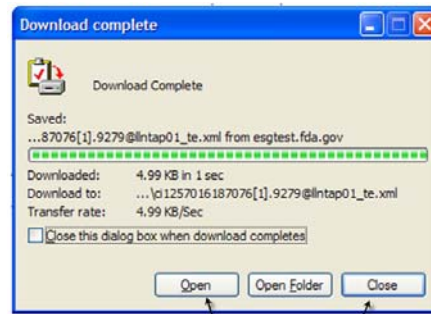
- Click the “Save” button in the “File Download” window prompt.

Saving the Error Message Document cont...



- Navigate to preferred location on your computer in which to store the error message.
- Click the “Save” button to save message in preferred location.

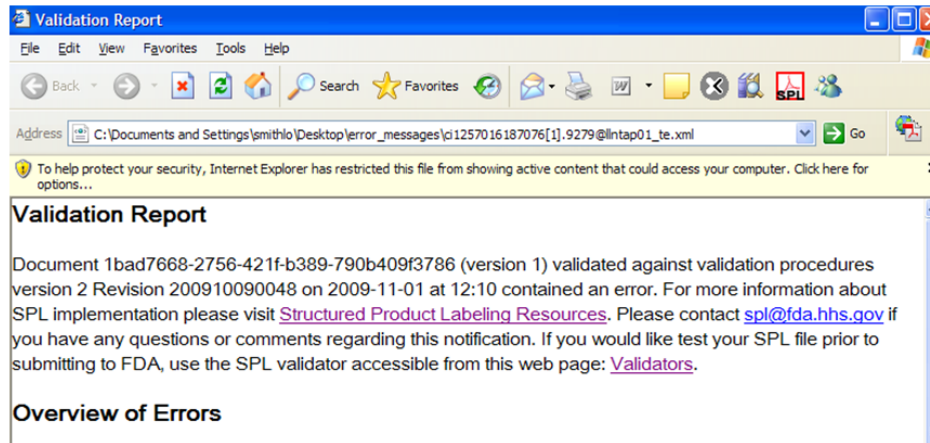
Completing Download



Select "Open" or "Close" buttons

- You can open the message from the "Download complete" window prompt
- You can also close the window and directly open from location on your computer where message was stored.

Review the Error Message



- Review the error message

Configuring PC to View Error Message

- If you are experiencing technical difficulties resulting in your inability to view the error message you have downloaded, we recommend that you follow these steps for Internet Explorer
 - Click the "Tools" menu and select "Internet Options".
 - Click the "Security" tab.
 - Click the "Custom level" button.
 - Scroll down to the "Miscellaneous" section.
 - Enable the "Access data sources across domains".
 - Click "OK" to accept the update.
 - Click "OK" to close the security dialog.

Test Your SPL R4 Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>
- NOTE
 - This validator tool is **NOT** connected to FDA database.
 - This tool assist you in detection of **90 – 95%** of technical errors in SPL documents.

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov URL. Below this is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories: Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates.' link with an arrow pointing to it. Below this is a paragraph explaining the council's role in coordinating data standards. At the bottom of the main content area is a link for 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)